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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,204	07/10/2006	Stanislaw Joseph Urbaniak	ABLE0032US.NP	6475

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOactions@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,204	URBANIAK ET AL.	
	Examiner	Art Unit	
	MICHAEL SZPERKA	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,11,12 and 14-18* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 2, 2010 has been entered.

Claims 3, 8-10, and 13 have been canceled.
Claims 1 and 11 have been amended.
Claim 18 has been added.
Claims 1, 2, 4-7, 11, 12, and 14-18 are pending in the instant application.
Claims 1, 2, and 4-7 stand withdrawn from consideration as being drawn to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons of record set forth in the restriction requirement mailed February 22, 2008.

Applicant still continues to traverse the restriction requirement. Applicant argues that the peptides must be “an immunologically effective linear peptide fragment” and that the prior art does not disclose such peptides.

This argument is not persuasive because “immunologically effective” reasonably means that the peptides can elicit an antibody response. Note that the 13mer peptides of Flug et al. (of record) were used to make polyclonal antibodies and thus they are "immunologically effective". Note further that all of applicant's arguments appear to hinge upon intended use limitations, which do not distinguish over the prior art unless they alter the structure of the resulting claimed product in a demonstrable manner. As has already been discussed, the intended use limitations do not alter the structure of the claimed products in such a fashion. Further note that the restriction requirement was made final in the office action mailed July 2, 2009 and that applicant's arguments do not appear to be different from those already of record.

Claims 11, 12, and 14-18 are under examination in this office action.

It should be noted that dependent claim 14 depends from canceled claim 13, and that claims 15 and 16 either directly or indirectly depend from claim 14. As such, the metes and bounds of claims 14-16 cannot be known with certainty and a rejection to this effect has been set forth in this office action. However, in the interest of compact prosecution, for statutes other that 35 USC 112 second paragraph, claim 14 has been interpreted to be dependent upon claim 11 and rejections have been set forth accordingly.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 11, 12, and 14-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement concerning the issue of “tolerance” has been withdrawn in view of applicant’s claim amendments received August 2, 2010 which removed this mechanistic limitation from the instant claimed invention.

It is noted that applicant has submitted the declaration by Mark Peakman as part of the arguments concerning the enablement rejection of record concerning "tolerance". Since this rejection has been withdrawn in view of applicant's claim amendments which remove "tolerance" as the mechanism of action from the instant claims, the declaration by Mark Peakman will not be discussed further.

4. Claims 11, 12, 14, 15, and 17 stand rejected and newly presented claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention for the reasons of record.

The office action mailed March 2, 2010 states:

> Applicant has amended the independent claim to recite "linear peptide fragment" and has argued that support for such an amendment can be found on line 31 of page 7. The text of that passage is as follows:
>
> > In the present invention a set of linear peptides with the polymorphism at every possible position in 15 mer peptides (see Figure I) was derived, and this was successful in identifying Leu-33-peptide specific responses.
>
> Thus, the context for the phrase "linear peptide" is limited to sequences of 15 amino acids. In contrast, the instant claims comprise no such length limitation. Indeed, the size of the peptide used in the instant claimed methods reasonably ranges from two consecutive amino acids all the way to full length GPIIIa in a reducing buffer (such that internal disulfide bonds are broken, resulting in a linear structure of covalent bonds between the amino acid residues). Given this discrepancy in scope between what is disclosed in the specification and what has been claimed, applicant's claim amendments appear to have introduced new matter into the presently claimed invention. In response, it is suggested that applicant either point out where additional support for the present limitation can be found or amend the claim to remove the offending material.

Applicant's arguments filed August 2, 2010 have been fully considered but they are not persuasive. Applicant argues that the above cited passage from the specification is only one example, and that support can also be found at page 7, lines 21-25.

This argument is not persuasive. The paragraph cited by applicant is as follows:

> Helper T-cells recognize antigen as linear peptides bound to MHC molecules and, immunodominant T-cell epitopes on an antigen can be identified, by challenging helper T-cells in vitro with linear peptides derived from the protein sequence of the antigen. The protein sequence of GPIIIa, which is the carrier molecule for HPA-Ia, has already been determined, enabling the preparation of synthetic HPA-Ia GPIIIa peptides corresponding to the HPA-Ia polymorphic region of the GPIIIa molecule.

It should be noted that the paragraph cited in the previous office action is found immediately after the above cited paragraph. Thus it is clear that the linear peptides contemplated by the specification are capable of being bound by MHC molecules and are of 15 amino acids in length. Note that as was discussed in the rejection of record,

no length limitation is provided in the instant claims such that the administered product can comprise full length GPIIIa in a reducing buffer, and that such a difference is scope between what has been claimed and what has been disclosed in the specification is considered to have introduced new matter into the claimed invention.

Applicant argues that the 15mers were only used initially by applicant due to scale, cost and expediency, but that once these were found it would be routine experimentation to identify additional peptides as evidenced by the declaration of Dr. Peakman.

This argument is not persuasive. As stated by Dr. Peakman, “it is well known in the field that the nature and length of N- and C- terminal flanking regions of a peptide can have profound effects on its ability to function in interactions with T cells". Thus, it is clear that different length peptides have distinct physical and profoundly different functional properties. Such profoundly different functions for different length peptides in interactions with T cells indicates that there is a large amount of unpredictability concerning activity of different length peptides, and there is no direction to any length or range of lengths disclosed in the specification excepting the 15 amino acid length limitation discussed in the rejection of record.

The rejection is maintained

5. Claims 11, 12, 14, 15, 17, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has claimed methods of administering a broad genus of “immunologically effective linear peptide fragments" of a human platelet antigen (HPA) to treat various disorders. The specification discloses the specific peptides consisting of SEQ ID NOs:1-30 and the following generic disclosure:

> Helper T-cells recognize antigen as linear peptides bound to MHC molecules and, immunodominant T-cell epitopes on an antigen can be identified, by challenging helper T-cells in vitro with linear peptides derived from the protein sequence of the antigen. The protein sequence of GPIIIa,

> which is the carrier molecule for HPA-Ia, has already been determined, enabling the preparation of synthetic HPA-Ia GPIIIa peptides corresponding to the HPA-Ia polymorphic region of the GPIIIa molecule.
>
> In the present invention a set of linear peptides with the polymorphism at every possible position in 15 mer peptides (see Figure I) was derived, and this was successful in identifying Leu-33-peptide specific responses.

No working examples are provided concerning administration of HPA peptides to a patient, and the only functional data is that some of the peptides of SEQ ID NOs:1-30 could stimulate T cells present in the PBMC of women who had developed anti-HPA antibody responses as a result of pregnancy.

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001, see especially page 1106 column 3).

In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412) 19 F. 3d 1559, the court noted:

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type

of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

The court has further stated that "Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

As was stated above, applicant has claimed the use of a genus of peptides based upon their functional properties of treating "conditions caused by exposure to an antithetical allele of a platelet by transfusion or during pregnancy" and of being "immunologically effective". However, as was also stated above, the specification does not disclose working examples comprising administration to treat any platelet disorder. Further, applicant has repeatedly argued in the August 2, 2010 response that the "linear peptide fragments" are not to be considered as being limited to 15 amino acids in length, and presumably applicant also does not believe that the claims are to be limited to the peptides consisting of SEQ ID NOs:1-30 as applicant has argued that the 15mers were used for scale, cost and expediency and that other sequences could be found by routine experimentation. However, the declaration of Dr. Peakman states that "it is well known in the field that the nature and length of N- and C- terminal flanking regions of a peptide can have profound effects on its ability to function in interactions with T cells". As such, it appears that the functional properties of the peptides used in the methods are very strongly tied to their structure, yet no structure other than that the peptides are linear are recited in the indicated claims. Further, given the statements by Dr. Peakman, the peptides consisting of SEQ ID NOs:1-30 are not representative species since alterations to the N- or C- termini, such as truncations, mutations, and additions, can profoundly alter their functional properties.

Therefore, a skilled artisan would reasonably conclude that there is no reasonable correlation between the recited functional properties and the genus of "linear peptides" used in the instant claimed methods. Thus, applicant was not in possession of the recited genus of peptides used in the instant methods at the time the instant

invention was filed and therefore was not in possession of methods of administering such peptides at the time the instant application was filed.

6. Claims 11, 12, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed broad methods of administering peptide fragments of human platelet antigen (HPA) to prevent and manage conditions caused by exposure to an antithetical allele of a platelet by transfusion or during pregnancy. No working examples, either in humans or animal models, of treating such disease states are provided. What is provided is data that PBMC from women who developed an anti-HPA antibody response during pregnancy could be stimulated to proliferate in the presence of one or more of peptides consisting of SEQ ID NOs:1-30.

The specification does not define the term prevention, and as such it is reasonable that they term encompasses 100% efficacy in 100% of patients upon whom the claimed administration method is practiced. As stated above, given the lack of working examples, no data it present to support such a level of efficacy. Further, prevention reasonably means that the condition never occurs (i.e. the patient shows no clinical signs and symptoms of the disease in question) yet as the instant specification discloses in paragraph [0005] there are no routine screening procedures for the conditions applicant wants to treat. Given that the conditions and disorders applicant wishes to treat are only diagnosed once clinical signs and symptoms become apparent, how can the instant methods achieve “prevention” since the conditions and disorders are already clinically manifest? Does applicant indent to treat the genus of all human beings to be the patient population upon whom the instant claimed administration methods are practiced?

Further, what peptide fragments are suitable for use in the instant claimed invention? The specification discloses the 15mer peptides consisting of SEQ ID NOs:1-

30, yet the instant claims are not so limited and applicant has repeatedly argued on the record that 15mer peptides are merely starting points and that other suitable peptides can be found by routine optimization. However, such peptides must be "immunologically effective" yet the meaning of this term, or how peptides are to be judged as being immunologically effective versus immunologically ineffective is not disclosed. The specification is required to provide guidance and direction concerning the claimed invention, and thus simply indicating that the "immunologically effective" peptides are the ones which work, especially in view of the fact that no working example of the instant claimed method has been provided, is not reasonable. Additionally, the declaration of Dr. Peakman states "it is well known in the field that the nature and length of N- and C- terminal flanking regions of a peptide can have profound effects on its ability to function in interactions with T cells". Thus, clearly there is a large amount of unpredictability in the claimed invention with regard to the specific sequence and structure of the peptide that is to be administered in the instant claimed methods, such unpredictability made even larger due to the lack of guidance concerning the manner in which "immunological efficacy" is to be ascertained.

Therefore, in view of the breadth of the claimed invention, the lack of guidance and working examples in the specification, and the unpredictability of the art as evidenced by the Peakman declaration, a skilled artisan would be unable to make and use the full breadth of the instant claimed invention without first conducting unpredictable research and experimentation.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11, 12, 14, 15, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the independent claims recite an “immunologically effective” linear peptide fragment. The phrase “immunologically effective” was present in the claims as originally filed, but the specification does not define what is meant by this term or indicate how such efficacy is to be determined and measured. Thus, the term "immunologically effective" is a relative term which renders the claims indefinite. Since the term "immunologically effective" is not defined by the claim and since the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This is especially true in view of the declaration by Dr. Peakman received August 2, 2010 which states that “it is well known in the field that the nature and length of N- and C- terminal flanking regions of a peptide can have profound effects on its ability to function in interactions with T cells".

9. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 14, depends from claim 13 which has been canceled. Thus, it is impossible to know the true metes and bounds of the claimed invention. Claims 15 and 16 depend directly or indirectly from claim 14 and thus share its problem of indefiniteness. Amending claim 14 to depend from claim 11 or rewriting claim 14 into independent form are possible ways to obviate this rejection.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Flug et al. (of record).

Flug et al. teach the administration of linear 13mer peptide fragments of GPIIIa comprising either the PLA^1 or PLA^2 polymorphisms to animals for the purpose of obtaining polyclonal antibodies (see entire document, particularly the left column of page 1965). Thus, the administered peptides were "immunologically effective" since they stimulated the proliferation of B cells (which are present in PBMC) which secreted peptide-specific antibody.

Therefore, the prior art anticipates the claimed invention.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 11, 12, 14-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-22 of copending Application No. 12/096,092 for the reasons of record.

As was stated in the July 2, 2009 and March 2, 2010 office actions:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims also recite methods of administering peptides to cause tolerization in a patient exposed to an antithetical allele. The copending methods recite that the tolerizing peptide is a T cell antigen and that the treated disorders include transfusion reactions. Thus the copending claims anticipate some of the instant claims and significantly overlap in scope with other claims of the instant invention.
>
> This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has argued that the instant application is earlier filed with regard to the '092 application, and that since applicant believes that their arguments are sufficient to remover all other grounds of rejection, applicant argues that this provisional rejection should be withdrawn and that the earlier filed application should be allowed to issue.

This argument is not persuasive since as discussed above, applicant's arguments and claim amendments have not resulted in all other rejections being withdrawn. As such, the provisional rejection is maintained.

14. Claims 11, 12, and 14-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-32 of copending Application No. 12/523,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the breadth of the instant claimed invention. Specifically, the copending claims recite administering HPA peptides of specific SEQ ID numbers to treat autoimmune thrombocytopenia. Note that such an administration will inherently stimulate proliferation of lymphocytes in the recipient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. No claims are allowable.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL SZPERKA whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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